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March 16, 2007

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1618

Attn: Mail Stop Amendment

Re: U.S. Utility Patent Application
Application No. 10/565,885; Filed: January 25, 2006
For: **Administration of Anti-Cytokine F(ab')₂ Antibody Fragments**
Inventors: LOPEZ DE SILANES *et al.*
Our Ref: 2399.0080000/JAG/LAV

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement Under 37 C.F.R. § 1.97(b);
2. Form PTO/SB/08A (1 sheet) listing twenty-three (23) documents (US1-US20 and FP1-FP3);
3. Form PTO/SB/08B (4 sheets) listing thirty-five (35) documents (NPL1-NPL35);
4. Copies of thirty-eight (38) cited documents (FP1-FP3 and NPL1-NPL35); and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
March 16, 2007
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.


Laura A. Vogel
Attorney for Applicants
Registration No. 55,702

LAV/U-W:trh:amr
Enclosures

652662_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LOPEZ DE SILANES *et al.*

Appl. No.: 10/565,885

Filed: January 25, 2006

For: **Administration of Anti-Cytokine
F(ab')₂ Antibody Fragments**

Confirmation No.: 8053

Art Unit: 1618

Examiner: *To Be Assigned*

Atty. Docket: 2399.0080000/JAG/LAV

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **FP1** to **FP3** and **NPL1** to **NPL35** are submitted herewith. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, **US1** to **US20**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language document **NPL18** cited on Form PTO/SB/08B:

Document **NPL18**, Maraboto Martinez, J.A., *et al.*, "Panorama Epidemiológico de las Intoxicaciones Causadas por Animales Ponzoñosos en la Población Derechohabiente del IMSS 1990-1998," in *3^a Reunión de Expertos en Envenenamiento*

por Animales Ponzosos, Instituto de Biotecnología, Universidad Nacional Autónoma de México, Alcapulco, Gro., México (February 17-19, 1999), is in the Spanish language. An English language translation of document NPL18 is attached as **NPL19**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

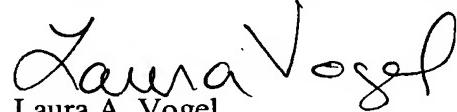
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.


Laura A. Vogel
Attorney for Applicants
Registration No. 55,702

Date: 3/16/07

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Equivalent of Form PTO/SB/08A (09-06)
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Substitution of Form 1449/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/565,885
				Filing Date	January 25, 2006
				First Named Inventor	LOPEZ DE SILANES, Juan
				Art Unit	1618
				Examiner Name	To Be Assigned
Sheet	1	of	1	Attorney Docket Number	2399.0080000/JAG/LAV

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)	MM-DD-YYYY		
US1		4,806,346	02/21/1989	Hum <i>et al.</i>	
US2		4,814,433	03/21/1989	Fredrickson	
US3		4,849,352	07/18/1989	Sullivan <i>et al.</i>	
US4		4,940,670	07/10/1990	Rhodes	
US5		5,328,834	07/12/1994	Ngo <i>et al.</i>	
US6		5,443,976	08/22/1995	Carroll	
US7		5,733,742	03/31/1998	Landon	
US8		5,888,511	03/30/1999	Skurkovich <i>et al.</i>	
US9		5,904,922	05/18/1999	Carroll	
US10		6,333,032	12/25/2001	Skurkovich <i>et al.</i>	
US11		6,448,054	09/10/2002	Poznansky <i>et al.</i>	
US12		6,534,059	03/18/2003	Skurkovich <i>et al.</i>	
US13		6,709,655	03/23/2004	Lopez de Silanes <i>et al.</i>	
US14		2003/0049725 A1	03/13/2003	Heavner <i>et al.</i>	
US15		2003/0215448 A1	11/20/2003	Skurkovich <i>et al.</i>	
US16		2003/0223995 A1	12/04/2003	Skurkovich <i>et al.</i>	
US17		2003/0224005 A1	12/04/2003	Skurkovich <i>et al.</i>	
US18		2003/0228310 A1	12/11/2003	Skurkovich <i>et al.</i>	
US19		2004/0062768 A1	04/01/2004	Skurkovich <i>et al.</i>	
US20		2004/0086508 A1	05/06/2004	Skurkovich <i>et al.</i>	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)			
	FP1	ES 2 106 183	11/01/1997	Therapeutic Antibodies Inc.	Abs
	FP2	WO 92/22324 A1	12/23/1992	Xoma Corporation	
	FP3	WO 01/58469 A1	08/16/2001	Wax <i>et al.</i>	

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Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/565,885
				Filing Date	January 25, 2006
				First Named Inventor	LOPEZ DE SILANES, Juan
				Art Unit	1618
				Examiner Name	To Be Assigned
Sheet	1	of	4	Attorney Docket Number	2399.0080000/JAG/LAV

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published		T ²
	NPL1	BECERRIL, B., <i>et al.</i> , "Cloning and characterization of cDNAs that code for Na ⁺ - channel-blocking toxins of the scorpion <i>Centruroides noxius</i> Hoffman," <i>Gene</i> 128:165-171, Elsevier Science Publishers B.V. (1993)		
	NPL2	CAIN, B.S., <i>et al.</i> , "The Physiologic Basis for Anticytokine Clinical Trials in the Treatment of Sepsis," <i>J. Am. Coll. Surg.</i> 186:337-351, American College of Surgeons (1998)		
	NPL3	CALDERON-ARANDA, E.S., <i>et al.</i> , "Neutralizing Capacity of Murine Seras Induced by Different Antigens of Scorpion Venom," <i>Toxicon</i> 31:327-337, Pergamon Press Ltd. (1993)		
	NPL4	CALDERON-ARANDA, E.S., <i>et al.</i> , "The use of synthetic peptides can be a misleading approach to generate vaccines against scorpion toxins," <i>Vaccine</i> 13:1198-1206, Elsevier Science, Ltd. (1995)		
	NPL5	COURAUD, F., <i>et al.</i> , "Two Types of Scorpion Toxin Receptor Sites, One Related to the Activation, the Other to the Inactivation of the Action Potential Sodium Channel," <i>Toxicon</i> 20:9-16, Pergamon Press Ltd. (1982)		
	NPL6	DEHESA-DÁVILA, M. and Possani, L.D., "Scorpionism and Serotherapy in Mexico," <i>Toxicon</i> 32:1015-1018, Elsevier Science Ltd. (1994)		
	NPL7	DEHESA-DÁVILA, M., <i>et al.</i> , "Clinical Toxicology of Scorpion Stings," in <i>Handbook of Clinical Toxicology of Animal Venoms and Poisons</i> , Ch. 18, Meier, J., and White, J., eds., CRC Press, Boca Raton, FL, pp. 221-238 (1995)		
	NPL8	Abstract of DICK, A.D., <i>et al.</i> , "Neutralizing TNF-alpha Activity Modulates T-cell Phenotype and Function in Experimental Autoimmune Uveoretinitis," <i>J. Autoimmun.</i> 11:255-264 (1998)		
	NPL9	EDMAN, P. and Begg, G., "A Protein Sequenator," <i>Eur. J. Biochem.</i> 1:80-91, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1967)		
	NPL10	FEKADE, D., <i>et al.</i> , "Prevention of Jarisch-Herxheimer Reactions by Treatment with Antibodies Against Tumor Necrosis Factor α ," <i>N. Engl. J. Med.</i> 335:311-315, Massachusetts Medical Society (1996)		

Examiner Signature	Date Considered
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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				First Named Inventor	LOPEZ DE SILANES, Juan
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Sheet	2	of	4	Attorney Docket Number	2399.0080000/JAG/LAV

NON PATENT LITERATURE DOCUMENTS					
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	NPL11	FOX, D.A., "Cytokine Blockade as a New Strategy to Treat Rheumatoid Arthritis," <i>Arch. Intern. Med.</i> 160:437-444, American Medical Association (2000)			
	NPL12	GARCÍA, C., <i>et al.</i> , "Isolation, Characterization and Comparison of Novel Crustacean Toxin with a Mammalian Toxin from the Venom of the Scorpion <i>Centruroides noxius Hoffman</i> ," <i>Comp. Biochem. Physiol.</i> 116B:315-322, Elsevier Science, Inc. (1997)			
	NPL13	KRUEGER, J.G., "The immunologic basis for the treatment of psoriasis with new biologic agents," <i>J. Am. Acad. Dermatol.</i> 46:1-23, American Academy of Dermatology, Inc. (January 2002)			
	NPL14	LEGROS, C., <i>et al.</i> , "Use of fusion protein constructs to generate potent immunotherapy and protection against scorpion toxins," <i>Vaccine</i> 20:934-942, Elsevier Science, Ltd. (2002)			
	NPL15	LICEA, A.F., <i>et al.</i> , "FAB Fragments of the Monoclonal Antibody BCF2 are Capable of Neutralizing the Whole Venom from the Scorpion <i>Centruroides noxius Hoffman</i> ," <i>Toxicon</i> 34:843-847, Elsevier Science Ltd. (1996)			
	NPL16	LISMAN, K.A., <i>et al.</i> , "Managing Heart Failure with Immunomodulatory Agents," <i>Cardiol. Clin.</i> 19:617-625, W.B. Saunders Co. (2001)			
	NPL17	LUGER, T., "Treatment of immune-mediated skin diseases: future perspectives," <i>Eur. J. Dermatol.</i> 11:343-347, accessed at http://www.john-libbey-eurotext.fr/en/revues/medecine/ejd/e-docs/00/01/88/A6/article.md , John Libbey Eurotext (2001)			
	NPL18	MARABOTO MARTINEZ, J.A., <i>et al.</i> , "Panorama Epidemiológico de las Intoxicaciones Causadas por Animales Ponzoñosos en la Población Derechohabiente del IMSS 1990-1998," in <i>3^a Reunión de Expertos en Envenenamiento por Animales Ponzoñosos</i> , Instituto de Biotecnología, Universidad Nacional Autónoma de México, Alcapulco, Gro., México (February 17-19, 1999)			
	NPL19	English translation of Maraboto Martínez, J.A., <i>et al.</i> , "Panorama Epidemiológico de las Intoxicaciones Causadas por Animales Ponzoñosos en la Población Derechohabiente del IMSS 1990-1998," in <i>3^a Reunión de Expertos en Envenenamiento por Animales Ponzoñosos</i> , Instituto de Biotecnología, Universidad Nacional Autónoma de México, Alcapulco, Gro., México (February 17-19, 1999)			
	NPL20	MARTIN, G.S., "Current Management Strategies for Severe Sepsis and Septic Shock," Presented at Chest 2001: 67th Annual Scientific Assembly of the American College of Chest Physicians, November 4-8, 2001, Philadelphia, PA, accessed online at http://www.medscape.com/viewarticle/412927 , Medscape Portals, Inc., 4 pages (2001)			

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				First Named Inventor	LOPEZ DE SILANES, Juan
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				Examiner Name	To Be Assigned
Sheet	3	of	4	Attorney Docket Number	2399.0080000/JAG/LAV

NON PATENT LITERATURE DOCUMENTS				
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	NPL21	NONNER, W., "Effects of <i>Leiurus</i> Scorpion Venom on the "Gating" Current in Myelinated Nerve," <i>Adv. Cytopharmacol.</i> 3:345-352, Raven Press (1979)		
	NPL22	POSSANI, L.D., <i>et al.</i> , "Scorpion toxins from <i>Centruroides noxius</i> and <i>Tityus serrulatus</i> ," <i>Biochem. J.</i> 229:739-750, Biochemical Society/Portland Press (1985)		
	NPL23	POSSANI, L.D., <i>et al.</i> , "Scorpion toxins specific for NA ⁺ -channels," <i>Eur. J. Biochem.</i> 264:287-300, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1999)		
	NPL24	POSSANI, L.D., <i>et al.</i> , "Peptides and genes coding for scorpion toxins that affect ion-channels," <i>Biochimie</i> 82:861-868, Editions Scientifiques Elsevier (2000)		
	NPL25	PRESENT, D.H., <i>et al.</i> , "Infliximab for the Treatment of Fistulas in Patients with Crohn's Disease," <i>N. Engl. J. Med.</i> 340:1398-1405, Massachusetts Medical Society (1999)		
	NPL26	QIAN, Y., <i>et al.</i> , "Topical Soluble Tumor Necrosis Factor Receptor Type I Suppresses Ocular Chemokine Gene Expression and Rejection of Allogenic Corneal Transplants," <i>Arch. Ophthalmol.</i> 118:1666-1671, American Medical Association (2000)		
	NPL27	STAPCZYNSKI, J.S., "Shock, Septic," Dire, D.J., <i>et al.</i> , eds., eMedicine.com Inc., accessed online at http://emedicine.com/EMERG/topic533.htm , eMedicine.com, Inc., 25 pages (2004)		
	NPL28	STRICHARTZ, G., <i>et al.</i> , "An Integrated View of the Molecular Toxicology of Sodium Channel Gating in Excitable Cells," <i>Ann. Rev. Neurosci.</i> 10:237-267, Annual Reviews, Inc. (1987)		
	NPL29	TORRES, P.F., and KIJLSTRA, A., "The role of cytokines in corneal immunopathology," <i>Ocul. Immunol. Inflamm.</i> 9:9-24, Swets & Zeitlinger (2001)		
	NPL30	ZAMUDIO, F., <i>et al.</i> , "Amino acid sequence and immunological characterization with monoclonal antibodies of two toxins from the venom of the scorpion <i>Centruroides noxius Hoffman</i> ," <i>Eur. J. Biochem.</i> 204:281-292, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1992)		

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2399.0080000/JAG/LAV					

NON PATENT LITERATURE DOCUMENTS					
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	NPL31	ZHU, S., et al., "Early Expression of Proinflammatory Cytokines Interleukin-1 and Tumor Necrosis Factor- α after Corneal Transplantation," <i>J. Interferon. Cytokine. Res.</i> 19:661-669, Mary Ann Liebert, Inc. (1999)			
	NPL32	International Search Report for International Patent Application No. PCT/MX02/00013, European Patent Office, Netherlands, mailed on August 16, 2002			
	NPL33	Dialog File 351, Accession No. 9271133, Derwent WPI English language abstract for Spanish Patent No. 2 106 183 (Document FP1)			
	NPL34	English language translation of Secretaría de Salud, "Pyrogen Tests," in: <i>Farmacopea de los Estados Unidos Mexicanos</i> , Vol. I, Secretaría de Salud, Mexico City, MX, pp. 334-335 (2000)			
	NPL35	English language translation of Secretaría de Salud, "Potency of Anti-Poison Sera," in <i>Farmacopea de los Estados Unidos Mexicanos</i> , Vol. II, Secretaría de Salud, Mexico City, MX, pp. 1756-1757 (2000)			

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